REMARKS

Examination of claims 1-14 is reported in the present Office Action. Claims 1-14 were rejected under 35 U.S.C. § 112, first paragraph. Claims 1 and 4-14 were rejected under 35 U.S.C. § 102(b). Each of these rejections is addressed as follows.

Amendments

Applicants add new claims 15 and 16. No new matter has been added.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-14 stand rejected under § 112, first paragraph based on the assertion that the teaching of applicants' specification is not commensurate in scope with the present claims. The rejection essentially turns on the assertion that it would require undue trial and error experimentation to screen myriad plants transformed with different nucleic acids encoding a constitutively active kinase of a MAPKKK or kinase domain thereof. This rejection should be withdrawn.

Applicants first point out that the Federal Circuit has made clear the level of teaching needed to enable a claim, and has repeatedly stated that a patent need not reiterate techniques known to skilled workers in a particular area of technology. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400

(Fed. Cir. 1988); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 954 (1987) ("A patent need not teach, and preferably omits, what is well known in the art."); *see also Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 231 U.S.P.Q. 649 (Fed. Cir. 1986) ("A patent applicant need not include in the specification that which is already known to and available to the public.").

In view of this standard, applicants submit that their specification clearly enables the subject matter presently claimed. In particular, given the teaching of the specification and the level of skill known in the art at the time the present application was filed, applicants submit that screening plants transformed with different nucleic acids encoding a constitutively active kinase of a MAPKKK or kinase domain thereof is routine, as outlined in applicants' specification, by employing standard techniques of molecular biology.

The Office has the initial burden to establish a reasonable basis to question enablement. In *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367, 369 (CCPA 1971), the court stated:

> a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

The MPEP (§ 2164.04) echoes the findings of *Marzocchi*:

> (I)t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise there would be no need for the Appellant to go to the trouble and expense of supporting his presumptively accurate disclosure.

In an attempt to cast doubt on the enablement aspects provided in the instant specification, the Office, without any evidence or scientific reasoning, simply states that "the ability of [] MAPKKK genes to induce stress resistance in transgenic plants cannot be extrapolated to all MAPKKK [genes]."

To the extent that the Office suggests not every MAPKKK gene would be successful, this does not mean the present claims are overbroad. The Federal Circuit has long held that it is not necessary for all possible embodiments of a claim to be operative in order for that claim to be enabled. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984). The proper test of enablement is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with the information known in the art without undue experimentation." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d. 1318 (Fed. Cir. 1985). In analyzing what constitutes undue experimentation, the MPEP (§ 2164.06) cites *In re Wands*, (858 F.2d 731, 8 USPQ2d 1400 (Fed Cir. 1988)):

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. (Emphasis added.)

At the time of filing, a skilled artisan, using no more than routine experimentation and the teachings of the present specification, could easily screen genes and plants falling within the claims. Such screening could easily be accomplished using standard techniques for generating and screening recombinant gene libraries and plants, and thus does not constitute undue experimentation. The present situation is, in all important aspects, indistinguishable from the facts in *Wands* in which the Federal Circuit held that the applicant's claim was enabled, despite the necessity for screening, because the process of screening was straightforward. It follows that the present claims are also enabled, even if some screening would be necessary to identify additional genes encoding functional polypeptides and plants falling within the scope of the present claims. As such, applicants have already demonstrated the feasibility of their invention by successful working examples, using routine methods.

Each of the methods described for isolating and characterizing the claimed plants involves standard techniques routinely used in the art of molecular biology at the time applicants filed their application. It is improper to find that such experimentation is "undue" simply because it requires some "trial and error," *W.L. Gore & Assoc. V. Garlock, Inc.* 721 F.2d 1540, 1557, 220 U.S.P.Q. 303, 316 (Fed. Cir. 1983), even when the experimentation is needed to weed out inoperative embodiments. *Atlas Powder v. E.I. DuPont deNemours*, 750 F.2d 1569, 1576-77, 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984).

All of the tools for expression of a constitutively active MAPKKK in a plant were

known when applicants filed their patent application: vectors containing promoters and terminators. Indeed, exemplary expression vectors, promoters, and terminators are described in the specification. Moreover, applicants in their specification describe several methods for introducing the vectors into host cells such as plant cells, and regenerating transformed plants. Plants expressing such genes are then selected according the methods described in the specification using standard techniques.

Applicants' specification cannot be found as failing to enable the claimed invention when the techniques required to practice the invention are disclosed in the specification and available to those skilled in the art. See *In re Wands, 858 F.2d* 731, 740, 8 USPQ2d 1400, 1406; *In re Strahilevitz*, 668 F.2d 1229,1232, 212 U.S.P.Q. 561, 563 (C.C.P.A. 1982). In short, no scientific hurdle and, consequently, no undue experimentation is required, or has been demonstrated by the Office. Case-by-case experimentation is expected by researchers in the biotechnological arts and is not undue. See *Johns Hopkins University v. Cell Pro, Inc.*, 152 F.3d 1342, 1360, 47 U.S.P.Q.2d 1705, 1718-19 (Fed. Cir. 1998); *In re Wands*, 858 F.2d 731, 740, 8 U.S.P.Q.2d 1400,1406-07 (Fed. Cir. 1988). This case is therefore distinguishable from those cases where scientific hurdles blocked the practicing of the claimed invention. For example, the patent applicant in *In re Goodman* admitted that there was a specific "major block" to practicing the claimed invention, i.e., expressing mammalian proteins in monocots. *In re Goodman*, 11 F.3d 1046,1051, 29 U.S.P.Q.2d 2010, 2014 (Fed. Cir. 1993). ("Goodman's

own 1987 article .... underscores the "major block" to using the claimed method in monocot plant cells.") No such hurdle or block has been shown to exist in this case, and applicants respectfully request that the enablement rejection be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claims 1 and 4-14 were rejected under 35 U.S.C. § 102(b) as anticipated by Tanksley *et al.* (U.S. Patent No. 5,648,599). Applicants respectfully traverse this rejection.

Claim 1 and claims 4-14, which refer directly or indirectly to claim 1, are drawn to a plant or a vector that include a nucleic acid that encodes a polypeptide comprising a constitutively-active kinase domain of a mitogen-activated protein kinase kinase kinase (MAPKKK) or a kinase domain thereof.

The Tanksley teaching is limited to the *Pto* gene. The Office fails to provide any reasoning or evidence as to why one skilled in the art would consider the *Pto* and MAPKKKs interchangeable, much less the kinase domains encoded by each gene. As previously stated, the *Pto* gene is not a MAPK, a MAPKK, or even a MAPKKK. The *Pto* gene does not encode a polypeptide having a regulatory domain that can be deleted to render the polypeptide constitutively active as found in MAPKKKs. Moreover, the Office provides no evidence that Tanksley teaches a "constitutively-active kinase domain of a mitogen-activated protein kinase kinase kinase (MAPKKK)" as presently claimed.

Tanksley therefore cannot anticipate claims 1 and 4-10 and this rejection should be withdrawn.

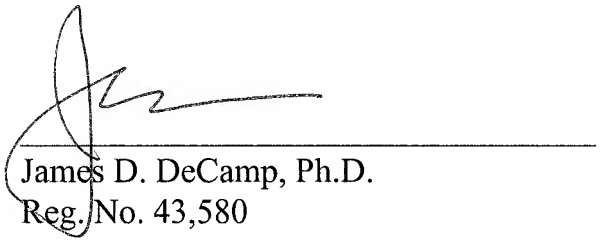
CONCLUSION

Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office Action for three (3) months, to and including May 3, 2006.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



Date: May 3, 2006

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